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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,059	05/22/2000	William J. Curatolo	PC8626BJTJ	2926

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EXAMINER	
CHOI, FRANK I	
ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/577,059	CURATOLO ET AL.	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *72-148* is/are pending in the application.

4a) Of the above claim(s) *77-79,87-92,130-132 and 140-145* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *72-76,80-86,93-129,133-139 and 146-148* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20060424,20060327*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 72-76,80-86,93-129,133-139, and 146-148 are rejected under 35 U.S.C. 103(a) as being unpatentable over Handsfield et al. in view of Urquhart (US Pat. 4,851,231), Edgren (US Pat. 4,522,625) for the reasons of record set forth in the prior Office Actions in further view of Etienne et al. (US Pat. 4,755,385) and Periti et al. (Abstract) and the further reasons below.

Handsfield, Urquhart and Edgren are cited for the same reasons as the prior Office Actions and the same are incorporated herein.

Etienne et al. disclose many macrolide antibiotics, such as erythromycin and AS-E 136 are sensitive to acidic media and are usually destroyed by the action of gastric juices (Column 1, lines 34-38). It is disclosed that it is well known to compress active substances with suitable excipients to form a tablet and coat a tablet with gastric juice-resistant lacquers such as cellulose acetate phthalate or hydroxyl-propylmethylcellulose phthalate which after leaving the stomach the lacquer dissolves in the intestinal juices and the active substance is dissolved and resorbed (Column 2, lines 25-53). It is disclosed that resistant to gastric juices means that the preparation should release virtually no active substance for a period between 30 minutes and 2 hours and having a pH solubility of between 5.5 and 6.8 or which releases the active substance at a pH of between 5.5 and 6.8, preferably, between 6.0 and 6.4 (Column 4, lines 5-10,60-68, Column 5,

lines 1-6). Tests are performed using USPXX apparatus at 100 rpm at pHs of 1.2, 4.5, 6.0, 6.2, 6.4 and 6.5 (Examples 1-8).

Periti et al. discloses that azithromycin is acid unstable (although exhibiting increased acid stability over older macrolide antibiotics) (Abstract).

The prior art discloses that azithromycin is effective for treating uncomplicated gonorrhea and drugs such as erythromycin, that induce nausea and vomiting should be administered to the intestine over time. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the in vitro criteria of Q0.25, Q1, Q2, Q4 and Q6 as determined by the claimed testing parameters. However, the prior art suggests the same as the prior art discloses that although erythromycin and azithromycin do have their differences, both erythromycin and azithromycin exhibit adverse gastric effects and are acid unstable (although azithromycin does have increased acid stability over erythromycin) and that resistant to gastric juices means that the preparation should release virtually no active substance for a period between 30 minutes and 2 hours and having a pH solubility of between 5.5 and 6.8 or which releases the active substance at a pH of between 5.5 and 6.8, preferably, between 6.0 and 6.4. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to control the release of azithromycin to be released at least 30 minutes after ingestion so as to avoid adverse gastric effects and any acid instability by using an enteric coating which dissolves preferably at a pH of between 6.0 and 6.4. As such, one of ordinary skill in the art would expect that for enteric coatings which dissolve at pHs of greater than 6.0 that substantially no active agent will be released until the pH of the surrounding media,

whether in vitro or in vivo, is at the appropriate pH. As such, such a dosage form will meet the criteria set forth in the claims.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

The mere fact that there are non-controlled formulations in the market does not refute the fact that acid sensitivity is a motivation for formulating a controlled release formulation. There could be any of a number of reasons why the manufacture selected non-controlled formulations; this does not mean that acid sensitivity is not a valid motivation to formulate controlled release formulations. For example, aspirin is sold as non-controlled release and controlled release formulations; the fact that aspirin is sold in a non-controlled release formulation does not make enteric coated aspirin any less obvious. The Applicant's reason or motivation to prepare a controlled release formulation does not have to be the same as the motivation in the prior. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See, e.g., In re Kahn, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006) (motivation question arises in the context of the general problem confronting the inventor rather than the specific problem solved by the invention); Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 1323, 76 USPQ2d 1662, 1685 (Fed. Cir. 2005) ("One of ordinary skill in the art need not see the identical problem addressed in a prior art reference to be motivated to apply its teachings."); In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972); In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991). As such, whether or not one of ordinary skill in the art would have recognized that azithromycin side-effects were locally mediated does not overcome the motivation in the

prior art. Again, the Applicant appears to argue that because azithromycin could be prepared as an immediate release formulation that there is no reason to prepare a controlled release formulation. However, the mere fact that immediate release forms of azithromycin are available does not make controlled release forms of azithromycin any less obvious.

Applicant reliance on Etienne is misplaced. AS-E 136 is not azithromycin and the prior art discloses that azithromycin is acid sensitive. As such, the problem with AS-E 136 does not apply to azithromycin. Since there is no requirement in a rejection based on a combination of references, that each reference alone disclose every component of the claimed invention, the mere fact that one or more references do not disclose one or more aspects of the claimed invention does not overcome the rejection herein.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 72-76, 80-86, 93-129, 133-139,146-148 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-76 of U.S. Patent No. 6,068,859 in view of Handsfield, Etienne et al. (US Pat. 4,755,385) and Periti et al. (Abstract).

Claims 1-76 disclose a controlled release dosage form in which not more than certain amounts of azithromycin are released within a time period after ingestion. "Controlled release" is defined to not include dosage forms which release more than 70% of their contained azithromycin within one half hour or less (Column 2, lines 9-12).

Hansfield, Etienne et al. (US Pat. 4,755,385) and Periti et al. (Abstract) are cited herein for the same reasons as above and are incorporated herein to avoid repetition.

The claims of the US Patent claim a controlled release azithromycin dosage form. The difference between the claims of the US Patent and the claimed invention is that the claims of the US Patent do not recite in vitro characteristics. However, the prior art amply suggests the same as the prior art discloses using USP criteria for determining release of active agents in various pH and the desirability of formulations which release at pHs greater than 6. As such, one of ordinary skill in the art would expect that formulation prepared under said criteria would exhibit in vitro characteristics the same or similar to that set forth in the claimed invention.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

The timewise extension of similar or obvious subject matter is not the only reason for judicially created doctrine of obviousness type-double patenting. For example, doctrine is designed to the avoid the harassment resulting from patents claiming said subject matter from being owned by different entities. See MPEP 804.02 [R-3] VI.

Therefore, the claimed invention, as a whole, would have been an obvious modification of the claims of US Pat. 6,068,859 to one of ordinary skill in the art at the time the invention was

made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Dr. Johann Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
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January 18, 2007

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